DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 25, 2014

Synthes USA Products, LLC
Mr. Mitch Ohiwa
Manager, Regulatory Affairs
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K141897
Trade/Device Name: Synapse System and OC Fusion System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP, MNH, MNI
Dated: July 11, 2014
Received: July 14, 2014

Dear Mr. Ohiwa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141897

Device Name
Synapse System

Indications for Use *(Describe)*

These Systems are intended for the following:

Hooks, Plate/Rods, Plates, Rods and Screws
When intended to provide stabilization as an adjunct to fusion of the cervical spine and occipitocervical junction (occiput-T3), the plate/rod, plates, rod, hook and screw (3.2 mm cortex) components of the Synthes CerviFix, Axon, OC Fusion and Synapse Systems are indicated for skeletally mature patients using allograft and/or autograft for the following:
• Degenerative Disc Disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
• Spondylolisthesis
• Spinal Stenosis
• Fracture/dislocation
• Atlantoaxial fracture with instability
• Occipitocervical dislocation
• Revision of previous cervical spine surgery
• Tumor
When used to treat these cervical and occipitocervical conditions, screws are limited to occipital fixation only.

Hooks and Rods
The rod and hook components are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Rods, Clamps, Screws, Nuts, Variable Axis Screws, Locking Screws, and Transverse Bars
The rods, clamps, screws, nuts, variable axis screws, locking screws, and transverse bars are intended to promote fusion following reduction of fracture/dislocation or trauma in the upper thoracic spine (T1-T3).
The use of these screws (3.5 mm, 4.0 mm and 4.5 mm cancellous, and 3.5 mm and 4.2 mm cortex) is limited to placement in T1-T3 in treating thoracic conditions only. They are not intended to be placed in or treat conditions involving the cervical spine.
The Synthes CerviFix, Axon, and Synapse Systems can also be linked to the Synthes Universal Spinal System using the 3.5 mm/6.0 mm and 4.0 mm/6.0 mm parallel connectors from that system and via the CerviFix tapered rods using lamina hooks, transverse process hooks, pedicle hooks, 4.2 mm screws, and the 5.0 mm/6.0 mm parallel connector.

Warning: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic (T4-T12), or lumbar spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141897

Device Name
OC Fusion System

Indications for Use *(Describe)*

The Synthes OC Fusion System is intended to provide stabilization as an adjunct to fusion of the occipital-cervical junction. A complete occipital-cervical-thoracic construct can be created by using hooks (C1-T3) and screws (T1-T3) that have been previously cleared within the Synthes CerviFix System, Synthes Axon System, and Synthes Synapse System.

The OC Fusion System is indicated for skeletally mature patients using allograft and/or autograft for the following indications:
• Degenerative disc disease of the cervical vertebrae (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
• Spondylolisthesis
• Spinal Stenosis
• Fracture/dislocation
• Atlanto/axial fracture with instability
• Occipital-cervical dislocation
• Revision of previous cervical spine surgery
• Tumors (primary and metastatic)
The use of screws is limited to placement in the occiput. Screws are not intended to be placed into the cervical spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(K) SUMMARY

A. Submitter Information

Submitter:	Synthes USA Products, LLC 325 Paramount Drive Raynham, Massachusetts 02767
Contact Person:	Mitch Ohiwa DePuy Synthes Spine 325 Paramount Drive Raynham, Massachusetts 02767
Telephone Number:	508-828-3225
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B. Date Prepared

September 2014

C. Device Name

Trade/Proprietary Name:	Synapse System OC Fusion System
Common/Usual Name:	Spinal interlaminal fixation orthosis
Device Classification and Regulation:	Class II, per 21 CFR 888.3050
Subsequent Regulation:	21 CFR 888.3070
Classification Product and Panel Code:	KWP (Orthopedic)
Subsequent Product and Panel Codes:	MNH (Orthopedic) MNI (Orthopedic)

D. Predicate Device Names

Primary Predicate:
Synthes Synapse System (most recently K133698)

Additional Predicates:
Synthes OC Fusion System (most recently K091689), and
Synthes CerviFix/Axon (K023675, most recently K030377 for CerviFix System)

E. Submission Purpose

The purpose of this submission is to include additional components in the Synapse and OC Fusion Systems.

F. Device Description

The Synapse System is a hook, pedicle screw, and rod spinal system which is designed to provide spinal fixation to allow for stabilization of spinal segments in skeletally mature patients as an adjunct to fusion. The Synapse System is composed of multiple components to allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. The Axon System and CerviFix System also included in the indications for use statement are additional hook, pedicle screw, and rod spinal systems. These systems consist of anchors including bone screws, pedicle screws and hooks; interconnection mechanisms including locking screws, set screws, parallel rod connectors, clamps, transverse bars, rod collars and nuts; longitudinal members including rods and rod/plates; and transverse connectors including transconnectors.

The OC Fusion System consists of occipital plates, occipital clamps, occipital screws, and rods intended to provide stabilization as an adjunct to fusion of the occipital-cervical junction. The OC Fusion System can be used with components from the Synthes CerviFix System including Axon and Synapse components to create a complete occipital-cervical-thoracic spinal construct.

Fixation of the rods included in the Synapse and OC Fusion Systems is achieved by using hooks from one of the aforementioned cleared systems. System components in the Synapse and OC Fusion Systems are implanted with Class I general use surgical instruments.

G. Indication for Use

Synapse System

Hooks, Plate/Rods, Plates, Rods and Screws
When intended to provide stabilization as an adjunct to fusion of the cervical spine and occipitocervical junction (occiput-T3), the plate/rod, plates, rod, hook and screw (3.2 mm cortex) components of the Synthes CerviFix, Axon, OC Fusion and Synapse Systems are indicated for skeletally mature patients using allograft and/or autograft for the following:

- Degenerative Disc Disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Fracture/dislocation
- Atlantoaxial fracture with instability
- Occipitocervical dislocation
- Revision of previous cervical spine surgery
- Tumor

When used to treat these cervical and occipitocervical conditions, screws are limited to occipital fixation only.

Hooks and Rods
The rod and hook components are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Rods, Clamps, Screws, Nuts, Variable Axis Screws, Locking Screws, and Transverse Bars
The rods, clamps, screws, nuts, variable axis screws, locking screws, and transverse bars are intended to promote fusion following reduction of fracture/dislocation or trauma in the upper thoracic spine (T1-T3). The use of these screws (3.5 mm, 4.0 mm and 4.5 mm cancellous, and 3.5 mm and 4.2 mm cortex) is limited to placement in T1-T3 in treating thoracic conditions only. They are not intended to be placed in or treat conditions involving the cervical spine.
The Synthes CerviFix, Axon, and Synapse Systems can also be linked to the Synthes Universal Spinal System using the 3.5 mm/6.0 mm and 4.0 mm/6.0 mm parallel connectors from that system and via the CerviFix tapered rods using lamina hooks, transverse process hooks, pedicle hooks, 4.2 mm screws, and the 5.0 mm/6.0 mm parallel connector.

Warning: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic (T4-T12), or lumbar spine.

OC Fusion System

The Synthes OC Fusion System is intended to provide stabilization as an adjunct to fusion of the occipital-cervical junction. A complete occipital-cervical-thoracic construct can be created by using hooks (C1-T3) and screws (T1-T3) that have been previously cleared within the Synthes CerviFix System, Synthes Axon System, and Synthes Synapse System.

The OC Fusion System is indicated for skeletally mature patients using allograft and/or autograft for the following indications:

- Degenerative disc disease of the cervical vertebrae (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Fracture/dislocation
- Atlanto/axial fracture with instability
- Occipital-cervical dislocation
- Revision of previous cervical spine surgery
- Tumors (primary and metastatic)

The use of screws is limited to placement in the occiput. Screws are not intended to be placed into the cervical spine.

H. Summary of Similarities and Differences in Technological Characteristics, Performance, and Intended Use

The proposed additional components to the Synapse and OC Fusion Systems share the same intended use, indications for use, and technological characteristics as the previously cleared components in the Synapse, OC Fusion, and CerviFix/Axon Systems.

I. Materials

The proposed additional components to the Synapse and OC Fusion Systems are manufactured from titanium aluminum niobium (Ti-6Al-7Nb (TAN)). The same material is used in the components of the previously cleared Synapse, OC Fusion, and CerviFix/Axon Systems. The material conforms to ASTM F1295-11 Standard Specification for Wrought Titanium-6Aluminum-7Niobium Alloy for Surgical Implant Applications and ISO 5832-11 Implants for surgery – Metallic materials – Part 11: Wrought titanium 6-aluminum 7-niobium alloy.

J. Performance Data

The proposed additional components to the Synapse System required no additional mechanical testing. The proposed additional components to the OC Fusion System were evaluated in mechanical testing including static compression bending testing, dynamic compression bending testing, static torsion testing, and dynamic torsion testing. The mechanical tests performed followed ASTM F2706-08, Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model. Test results and analyses showed that the proposed components to the Synapse and OC Fusion Systems were substantially equivalent to or better than the predicate devices.

K. Conclusion

The substantial equivalence justification demonstrates that the proposed additional components to the Synapse and OC Fusion Systems are as safe, as effective, and perform as well as the predicate components in the Synapse, OC Fusion, and Axon Systems.